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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,490	10/03/2003	Derek Lydiate	11089.0003.NPUS01	8191
27194	7590	05/13/2009		
HOWREY LLP-CA C/O IP DOCKETING DEPARTMENT 2941 FAIRVIEW PARK DRIVE, SUITE 200 FALLS CHURCH, VA 22042-2924			EXAMINER ZHENG, LI	
			ART UNIT 1638	PAPER NUMBER
			MAIL DATE 05/13/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/678,490	Applicant(s) LYDIATE ET AL.	
	Examiner LI ZHENG	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/22/2008; 3/24/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

9DETAILED ACTION

1. Applicants' amendment to claims 1 and 14 in the reply filed on January 26, 2009 is acknowledged.

Claims 1-8, 10 and 14 are pending and examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The rejections and objection not set forth in this action are withdrawn.

Claim Rejections - 35 USC § 112

New Matter

4. Claims 1-8, 10 and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 have been amended to recite "the first, second and third coding regions encode proteins that confer no adaptive advantage, are benign to the plant and are not

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antibiotic resistant". Applicants point to support for the phrase in the instant specification on page 3, lines 12-19 and the paragraph bridging pages 71-72 (response, 4th paragraph of page 5). However, the specification only supports that the selection marker genes are otherwise benign and confer no adaptive advantage. Therefore the amendments are considered as NEW MATTER..

Claim Rejections - 35 USC § 103

5. Claims 1-8, 10 and 14 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Fabijanski et al. in view of Mason et al. and Chou et al., for the reasons of record stated in the Office action mailed February 20, 2008. Applicants traverse in the paper filed May 20, 2008. Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue that the method Fabijanski et al. is designed for different purpose (response, the paragraph bridging pages 6-7).

The Office contends that even if the method Fabijanski et al. may be designed for different purpose, Fabijanski et al. in view of Mason et al. and Chou et al. teach all the steps of instant invention.

Applicants further argue that Fabijanski et al. disclose that the novel trait must be linked to the lethal gene to ensure that the novel trait can not persist in related species by transfer through sexual crossing (response, the paragraph bridging pages 6-7).

The Office contends the instant claims only require the tag gene (conditional lethal gene) to be in the first nucleotide sequence and the novel trait gene (gene of interest) to be in the second nucleotide sequence. The method of Fabijanski et al. meets such requirement (Figure 3). However, the instant claims do not exclude that the second nucleotide sequence further a second lethal gene linked to the trait gene given the open language "comprising".

Applicants argue that the method of Fabijanski et al. does not disclose a second nucleotide sequence including a repressor and a coding region of interest and do not disclose a selection strategy that is benign to the plant (response, the paragraph bridging pages 6-7).

The Office contends that Fabijanski et al. teach a second nucleotide sequence comprising a new trait sequence (corresponding to a second regulatory region in operative association with a second coding region) and repressor 2 gene (corresponding to a third coding region encoding a repressor capable of binding to the operator sequence thereby inhibiting expression of the first coding region) (Figure 3). Further, Fabijanski et al. also teach using oncogene 1 and 2 as a selection marker (Example 5, columns 33-35; also Table 1) which is similar to the conditionally lethal gene, *iaaH*, as disclosed in Example 5 of the instant specification. Therefore, Fabijanski et al. teach a selection strategy that is benign to the plant.

Further, Applicants argue that pCG-2 transformation vector includes a kanamycin resistance gene, which teaches away from instant invention (response, page 7, 2nd paragraph).

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The Office contends that Fabijanski et al. still teach all the limitations set forth by the claims and none of the first, second and third coding regions encode proteins conferring kanamycin resistance.

Applicants further argue that the addition of Mason et al. and Chou et al. does not remedy the deficiencies of Fabijanski et al. and that a person skilled in the art would have to ignore the specific teachings of Fabijanski et al. that any desirable trait must be linked with a lethal gene and that antibiotic resistance is suitable selection strategy (response, page 7, 3rd paragraph).

The Office contends that as discussed above, the instant claims do not have a limitation that excludes the gene of interest from being linked to a lethal gene. Further, none of the first, second and third coding regions encode proteins conferring antibiotic resistance.

Double Patenting

6. Claims 1-8, 10 and 14 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18-24 of copending Application No. 10/719,996 in view Mason et al.

Applicants wish to postpone the response to this rejection until the claims are otherwise allowable (page 8, 2nd paragraph). The rejection is maintained.

7. Claims 1-8, 10 and 14 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18, 21 and 24 of copending Application No. 10/995,951 in view Mason et al.

Applicants wish to postpone the response to this rejection until the claims are otherwise allowable (page 8, 2nd paragraph). The rejection is maintained.

Summary

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Zheng whose telephone number is 571-272-8031.

The examiner can normally be reached on Monday through Friday 9:00 AM - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ashwin Mehta/

Primary Examiner, Art Unit 1638